

# COLLAMATRIX

JUN 16 2010

*510(k) summary*  
Summary information

K09335  
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## 1. Date Prepared

August 1, 2009

## 2. Submitter name and address

Collamatrix Inc.  
1F, No.50-1, Keyan Road, Jhunan Science Park,  
Miaoli County, 350, Taiwan

## 3. Contact person

Name: Dennis J. N. Seah  
Tel: + 886 2 7711 3699  
Fax: + 886 2 7711 3599

## 4. Device names

Propriety name: CollaWound ART  
Common name: Antimicrobial wound dressing  
Classification name: Dressing, Wound

## 5. Device classification

Regulatory class: Unclassified  
Product code: FRO

## 6. Device description

CollaWound ART is a wound dressing comprised of collagen and polyhexamethylene biguanide (PHMB). The collagen is prepared from pig skin. CollaWound ART absorbs wound exudates and forms gel-like structure that maintains a moist microenvironment at

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the wound bed and aids in granulation tissue formation and re-epithelialization. The dressing acts as a protective barrier to the invasion of foreign microorganisms. The PHMB content is intended to reduce or prevent microbial colonization or growth on the device.

### 7. Intended use

CollaWound ART is a wound dressing intended for use as a barrier to resist microbial colonization within the dressing and reduce microbial penetration through the dressing. CollaWound ART will be used for the management of partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds.

### 8. Statement of Substantial equivalence

CollaWound ART is a PHMB-containing wound dressing device similar to predicate PHMB-containing devices that are previously approved by the agency and allowed for marketing towards the management of wounds.

#### Predicate devices are listed below

Trade name: FortaDerm™ Antimicrobial PHMB Wound Dressing coated with 0.1% Polyhexamethylene Biguanide Hydrochloride (PHMB) (K051647)

Company: Organogenesis Inc.

Trade name: XCell Antimicrobial Cellulose Wound Dressing (K024054)

Company: Xylos® Corporation

The proposed device, CollaWound ART, is another PHMB-containing wound dressing that is quite similar with respect to the indication for use, technological characteristics and material to the above devices in terms of the substantial equivalency under the 510(k) regulations.

### 9. Safety and effectiveness

Biocompatibility tests have confirmed that CollaWound ART meets the requirements

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stated in the FDA Blue book memorandum G95-1 and ISO 10993. The following studies were conducted:

- (a) Cytotoxicity
- (b) Irritation test
- (c) Sensitization
- (d) Systemic toxicity test
- (e) Genotoxicity
- (f) Hemocompatibility/hemolysis
- (g) Pyrogenic test
- (h) Release kinetic
- (i) Antimicrobial effectiveness study

### 10. Conclusion

CollaWound ART is essentially equivalent in indication for use, technological characteristics, material, safety and effectiveness to the commercially available predicate device, and therefore meets the requirements as defined in 21 CFR § 807.



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

JUN 1 8 2010

Collamatrix, Inc.  
% Mr. Dennis J.N. Seah  
1F, No. 50-1, Keyan Road, Jhunan Science Park  
Miaoli County, 350  
Taiwan

Re: K093351  
Trade/Device Name: CollaWound ART  
Regulatory Class: Unclassified  
Product Code: FRO  
Dated: May 10, 2010  
Received: May 14, 2010

Dear Mr. Seah:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

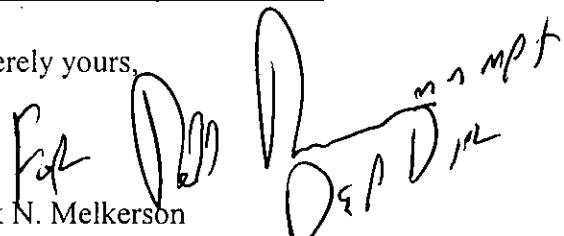
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. Dennis J.N. Seah

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

  
Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### **Statement of indications for use**

510(K) Number (if known): K093351

Device Name: CollaWound ART

#### Indications for Use:

CollaWound ART is a wound dressing intended for use as a barrier to resist microbial colonization within the dressing and reduce microbial penetration through the dressing. CollaWound ART is intended for the management of wounds including:

- partial and full thickness wounds
- pressure ulcers
- venous ulcers
- diabetic ulcers
- chronic vascular ulcers
- tunneled/undermined wounds
- surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, wound dehiscence)
- trauma wounds (abrasions, lacerations, second-degree burns, and skin tears)
- draining wounds

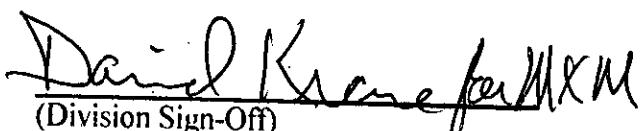
Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Surgical, Orthopedic,  
and Restorative Devices

510(k) Number K093351